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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,631	03/01/2002	Stephan Jaeger	022101-001500US	3750

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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,631	JAEGER, STEPHAN	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *50-63* is/are allowed.

6)☒ Claim(s) *34-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed August 11, 2005 is acknowledged and has been entered. Claims 1-33 have been canceled. Claims 50-63 have been added. Claims 34-53 are pending. All of the arguments have been thoroughly reviewed and considered but are deemed moot in view of the new grounds of rejections. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Rejections

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 34-37, 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gagnor et al (Nucleic acids Research, vol. 17, no. 13, pages 5701-5114) in view of Locatelli et al (WO 00/29613, May 2000). Regarding claims 34, 37, 40, Gagnor et al teach a composition comprising a target nucleic acid and a control nucleic acid (ps-β-I and ps-α-II), wherein said control nucleic acid comprises at least one contiguous sequence of at least 8 (clm 9) or at least 10 (clm 22) nucleotides in length essentially parallel complementary to said target nucleic acid region (see Figure 1, page 5108 and page 5110, first paragraph, under "Results", lines 1-10). Gagnor et al differs from the instant invention in that the reference does not teach wherein the composition comprises a thermostable polymerase and two sets of primers for target and control nucleic acid. However, Gagnor et al do teach wherein the composition comprises primers/probes and comprises a primer and/or probe binding site for use in a RT-PCR reaction and hybridization reaction (page 5109 to 5110, section entitled "Materials and Methods").

Locatelli et al teach composition comprising a target nucleic acid, wherein said target nucleic acid is DNA and calibrator (control nucleic acid), multiple sets of primers for the target and control nucleic acid and thermostable polymerase, which can be use in quantitative amplification and hybridization reactions in a single reaction vessel (page 4, line 23 to page 5, line 10).

Therefore, in view of the foregoing, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have modified the composition as taught by Gagnor et al to encompass primers for both the target and control nucleic acid along with a thermostable polymerase for use of the composition in quantitative detection of nucleic acids which can be performed in a single reaction vessel as taught by Locatelli et al.

Regarding 35-36, Gagnor et al teach the composition of claim 9, wherein said target nucleic acid comprises a primer binding site or a probe binding site and said control nucleic acid comprises a sequence that is parallel complementary to the primer binding site or probe binding site of the target nucleic acid (Figure 1, page 5108; page 5110, first paragraph, under "Results", lines 1-10 and page 5112, lines 3-7).

Regarding claim 38, Gagnor et al teach the composition of claim 9, wherein the target nucleic acid is an RNA molecule (Figure 1 and page 5110, first paragraph, under "Results", lines 1-10).

Regarding claim 41, Gagnor et al teach the composition of claim 10, further comprising a primer or probe (aps-β-I and aps-α-II) that binds to the primer-binding site or the probe-binding site (Figure 1, page 5108).

Applicant traversal and Examiner's response

5. Applicant traverses the rejection on the following grounds: Applicant states that the Gagnor reference is directed to using oligonucleotide to block nucleases. Applicant states that Gagnor only uses the oligonucleotides as gene control agents to block transcription. Applicant contends that even if one of skill in the art were motivated to amplify something from Gagnor et al, they would amplify the RNA to see if the nuclease has been blocked by the oligonucleotides. Applicant states that this interpretation does not result in a composition comprising primers to amplify or probes to detect each of the two nucleic acids. Applicant states that the cited art does not include all of the elements of the claims, e.g., target and control nucleic acid and primer and probes to amplify or detect each of the target and control nucleic acids. Applicant states that if the Examiner's interpretation is correct the oligonucleotide in Gagnor et al is the control nucleic acid, because at least one of the oligonucleotides in Gagnor et al is parallel complementary to the RNA. Applicant argues that although the Examiner did not present a clear explanation on this issue, this interpretation require amplification of the oligonucleotide itself if the reference included all elements of the claims. Applicant states that one skill in the art would not have been motivated to amplify the oligonucleotides itself because the oligonucleotides are too short and its amplification would serve no purpose. Applicant asserts that indeed the α-oligonucleotides described in Gagnor et al may hybridize to RNA, but there is no evidence that a polymerase would add nucleotides to their ends. Applicant states that not only does the combination of reference fail to teach the invention claimed, even if those of skill were motivated to amplify the nucleic acids as the Examiner suggests, (which those of skill were not), the combination would not work because of the material used by Gagnor et al.

6. All of the arguments have been thoroughly reviewed and considered but they are not found persuasive for the reasons that follows: In response to Applicant's arguments concerning the use of the oligonucleotides of Gagnor et al, it is noted that Applicant's claims are not drawn to "a method" but to "a product". The limitation "for amplification" as recited in the claims is "an intended use" of the primers. MPEP states that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim (See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963)). The claims as written only require a target and a control nucleic acid that comprises at least one contiguous sequence of at least 8 nucleotides in length essentially parallel complementary to said target nucleic acid region or the complementary strand of said target nucleic acid region and primers of the target and primers of said control. As stated earlier the limitation "for the amplification of the target" and "for the amplification of the control.." is an intended use limitation of the sets of primers. In regards to Applicant's arguments that the oligonucleotides of Gagnor any hybridize to RNA, but there is no evidence that a polymer would add nucleotides to their ends, it is noted that contrary to Applicant's arguments, Gagnor does carry out RT-PCR in the presence of primers as well as hybridization. Again, Applicant is reminded that the claims are not drawn to a method but rather a product with intended use limitations. No amplification or PCR is required but rather is an intended use of the composition. According the Examiner maintains that Gagnor is valid.

5. Claims 42-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gagnor et al in view of Locatelli as previously applied above and further in view of Ahern, H. (The Scientist, vol. 9, No. 15, pages 20-24, July 1995). Regarding claims 42, 43, 45, and 46, Gagnor et al in view of Locatelli et al teach the composition as previously described above. Locatelli et al further teaches the use of the composition in the form of kit.

In a scientific article, Ahern teaches the advantages of a kit and provides motivation for combining reagents in the form of a kit. Ahern teaches that a kit provides convenience, time management and ease of practicing to the investigator (page 23, second-forth paragraphs). Therefore, in view of the teaching of Ahern, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have combined the composition as taught by Gagnor et al in view of Locatelli et al in the form of a kit for the obvious benefits of convenience, time management and ease of practicing to the investigator as suggested by Ahern.

Regarding claims, 47, 48, Gagnor et al teach the composition of claim 42, wherein said target nucleic acid comprises a primer binding site or a probe binding site and said control nucleic acid comprises a sequence that is parallel complementary to the primer binding site or probe binding site of the target nucleic acid (Figure 1, page 5108; page 5110, first paragraph, under "Results", lines 1-10 and page 5112, lines 3-7).

Regarding claim 44, Gagnor et al teach the composition of claim 42 wherein the target nucleic acid is an RNA molecule (Figure 1 and page 5110, first paragraph, under "Results", lines 1-10).

Regarding claim 49, Gagnor et al teach the composition of claim 48, further comprising a primer or probe (aps-β-I and aps-α-II) that binds to the primer-binding site or the probe-binding site (Figure 1, page 5108).

Conclusion

7. Claims 50-63 are free of the prior art because no prior art was found teaching or suggesting a composition comprising a target and control nucleic acids, primers for both the target and control, and a control probe and a target probe which detects amplified products and further wherein the control probe is more than 80% parallel complementary to the target probe or the nucleotides complementary to the target probe. The closest prior art; Weller et al (Applied and Environmental Microbiology, July 2000, vol. 66, no. 7, pages 2853-2858) teach a composition comprising a target nucleic acid and a control nucleic acid and primers for amplification of said control nucleic acid, a control probe and a target probe, wherein said control probe detects amplified control nucleic acid and the target probe detects amplified target nucleic acid. Weller set al differs from the instant invention in that they do not teach wherein the control probe is more than 80% parallel complementary to the at least 8 nucleotide of the target probe or at least 8 nucleotides complementary to the target probe. No directionally as defined by Applicant in the use of the term "parallel complementary" is given in the prior art for the composition as described therein. Tchurikov et al (Federation of European Biochemical societies, vol. 297, Number 3, apges 233-236, February 1992) teach hybridization experiments using parallel complementary DNA probes. The reference differs from the instant invention in that it does not teach the use of the probes in quantitative and/or real-time PCR assays. No

motivation could be found in the prior art for combining the probes with a quantitative PCR assay. Accordingly, an obviousness rejection against the claims could not be made.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Cynthia Wilder

CYNTHIA WILDER
PATENT EXAMINER
10/31/2005